Clinical outcome of submerged vs. non-submerged implants placed in fresh extraction sockets

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Abstract
Aim: The aim of this study was to compare the clinical outcome of submerged vs. non-submerged tapered implants placed into fresh extraction sockets.

Materials and methods: A prospective, controlled, multicenter, randomized, clinical trial has been performed in two centers in Rome and Torino (Italy). Thirty healthy patients were recruited according to the following inclusion criteria: need for an immediate post extraction implant, ages between 18 and 70, horizontal defect depth < 2 mm, smokers < 10 cigarettes/day and absence of any circumstance or condition that could represent contraindications to implant surgery. The patients were randomly allocated to submerged or non-submerged treatment groups immediately after flap elevation and tooth extraction. Submerged implants were exposed 8 weeks after the first surgery; all implants were loaded with provisional restorations 12 weeks after the first surgery and with definitive restoration 12 weeks thereafter. Clinical and radiographic parameters were evaluated at baseline, at implant loading and at the 1-year follow-up visit.

Results: The results showed statistically significant differences between the two groups in the mean value of keratinized tissue (KT) height after surgery that was significantly reduced for submerged implants when compared with transmucosal implants (mean reduction of KT at year follow-up: T group 0.2 mm, S group 1.3 mm; P = 0.007).

Conclusion: Similar outcomes were found for submerged and non-submerged implants placed in fresh extraction sockets with a horizontal peri-implant defect smaller than 2 mm, except for a reduction of KT in the submerged group. Either with a submerged or a non-submerged procedure, 1 mm of mean soft tissue recession is seen after 1 year when compared with the pre-extraction situation.

Uneventful healing of implants placed immediately following tooth extraction has been extensively reported [Lazzara 1989; Chen et al. 2004]. The earlier studies advocated complete soft tissue closure over the implant to guarantee osseointegration [Lazzara 1989; Becker et al. 1994]. Various surgical procedures have been proposed for immediate implant placement in extraction sockets: submerged or non-submerged techniques with or without guided bone regeneration (GBR).

Some studies demonstrated good results combining submerged healing of immediate implants with GBR with non-resorbable or resorbable membranes [Becker & Becker 1990; Schwartz-Arad & Chaushu 1997; Nemcovsky et al. 2000; Goldstein et al. 2002; Chen et al. 2005] with bone graft alone [Becker et al. 1994; Schwartz-
Material and methods

A prospective, controlled, multicenter, randomized, clinical trial has been performed in two centers in Rome and Torino (Italy) in private practice settings. Patients were recruited according to the following inclusion criteria: need for an immediate post extraction implant procedure (Type 1 procedure according to the ITI consensus) (Häärmerle et al. 2004) to replace maxillary incisors, canines and premolars or mandibular canines or premolars, and age between 18 and 70.

The exclusion criteria at the screening visit were all the systemic diseases that could interfere with implant therapy, uncontrolled periodontitis, probing depth >4 mm at the adjacent teeth, inadequate oral hygiene, heavy smoking (>10 cigarettes/day) and adjacent implants. It was decided that if, at the moment of placement, the horizontal distance between the implant and the bony walls of the socket [horizontal defect depth (HDD)] was >2 mm the patients should be included in the category ‘intend to treat’ and should not be evaluated for the study purposes.

The patients were asked to participate in this study and were enrolled after meticulous explanations on the study protocol and after providing detailed answers to their questions. All the included patients signed an appropriate informed consent to the treatment.

Some authors reported that horizontal defects around immediate implants in extraction sockets could heal without any grafting or barrier procedure with a non-submerged approach (Botticelli 2004; Chen et al. 2007).

Studies that compare submerged and non-submerged healing procedures for implants placed in extraction sockets are lacking.

There is evidence that if the horizontal distance between the implant body and the socket wall [horizontal defect depth (HDD)] is <2 mm, a graft is not necessary for implant integration (Paolantonio et al. 2001; Chen et al. 2004). Some manufacturers have introduced a tapered implant design for post-extraction placement with the aim of both reducing the distance from the socket wall and the implant itself, and increasing primary stability.

The aim of this study was to compare the survival, success rate and clinical behavior of submerged vs. non-submerged tapered implants placed into fresh extraction sockets presenting HDD <2 mm without any augmentation procedure.
Modified plaque index (mPI) for oral implants (Mombelli et al. 1987) was recorded at implant provisional loading at implant definitive loading and at 1-year follow-up. Four measurements were taken around each implant: mesial, distal, buccal and lingual/palatal.

Peri-implant probing depth (PPD) was measured at implant provisional loading, at implant definitive loading and at 1-year follow-up. Four measurements were taken around each implant: mesial, distal, buccal and lingual/palatal.

Bleeding on probing (BOP) around the implants was measured at implant provisional loading, at implant definitive loading and at 1-year follow-up. Four measurements were taken around each implant: mesial, distal, buccal and lingual/palatal.

Height of KT, measured as the distance from the most apical point of the gingival margin to the muco-gingival line, was recorded before tooth extraction, at the moment of implant loading with provisional, at implant definitive loading and at 1-year follow-up.

Table 1. Study chart

<table>
<thead>
<tr>
<th>Time</th>
<th>Submerged group</th>
<th>Non-submerged group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening</td>
<td>Screening</td>
</tr>
<tr>
<td>0</td>
<td>Extraction, implant placement, allocation to treatment group</td>
<td>Extraction, implant placement, allocation to treatment group</td>
</tr>
<tr>
<td>8 weeks</td>
<td>Implant exposure</td>
<td>None</td>
</tr>
<tr>
<td>12 weeks</td>
<td>Loading with provisional</td>
<td>Loading with provisional</td>
</tr>
<tr>
<td>6 months</td>
<td>Loading with definitive</td>
<td>Loading with definitive</td>
</tr>
<tr>
<td>12 month</td>
<td>6-month follow-up</td>
<td>6-month follow-up</td>
</tr>
<tr>
<td>18 months</td>
<td>12-month follow-up</td>
<td>12-month follow-up</td>
</tr>
</tbody>
</table>

Variation of soft tissue position (REC). Three measurements were taken for each implant site (Fig. 3):

- **DP–IM**: Distance between the distal papilla and the adjacent tooth incisal margin.
- **GM–IM**: Distance between buccal gingival margin and the line connecting incisal margins of adjacent teeth.
- **MP–IM**: Distance between the mesial papilla and the adjacent tooth incisal margin.

These values were recorded before tooth extraction, at implant loading with provisional, at implant definitive loading and at 1-year follow-up.

The differences between the measurements taken before tooth extraction and the measurements taken at different stages of treatment were reported as recession values (REC).

All clinical measurements were taken in vivo with the aid of a UNC periodontal probe and their values were recorded to the nearest 0.5 mm.

Crestal bone levels (CBL): distances from the implant shoulder to the most coronal bone to implant contact measured on X-rays with a millimeter ruler to the nearest 0.5 mm. Two measurements were taken for each implant: mesially and distally.

Clinical measurements were performed by two different operators [one for each center]. In order to limit the inter-examiner variability, a preliminary calibration meeting was arranged before study initiation. The investigators discussed the study parameters together and agreed on the same measuring methods. Then an inter-examiner reliability test was performed for the clinical measurements: both operators independently took and recorded the studied parameters on a sample of 10 patients with implant-supported prostheses who were not part of this study, but agreed to be part of the calibration process.

The intra-examiner reliability was calculated with the Wilcoxon test separately for the two operators recording all the clinical parameters at the screening visit and after 1 week. This procedure was repeated at the moment of loading with provisional restoration and 1 week later for the parameters that could not be evaluated at baseline (such as PPD and BOP). The same operator measured all the X-rays of both the study centers and, consequently, only the intra-examiner reliability test was performed. The measurements taken on baseline and the final X-rays were taken twice at an interval of 2 months.

No significant mean difference was found both for clinical and for radiographic repeated series of measurements.
For numeric parameters such as PPD, KT, REC and CBL mean, standard deviation and nonparametric 95% confidence intervals (CI) of the measurements were calculated for each group. The comparison within groups was performed with the Wilcoxon test. The comparison between different groups was performed by means of the Mann–Whitney test. For nominal measurements such as BOP and plaque index (PI), the comparisons were made with the aid of the χ² test or Fisher’s exact when distributions with small frequencies were considered.

The level of significance was set at P < 0.05. Because six endpoints were evaluated a Bonferroni correction has been used (0.05/6), thus leading the level of significance to P < 0.008.

Results

Thirty implants were placed, 14 submerged and 16 non-submerged. One implant belonging to the non-submerged group failed before loading. The overall 1-year survival rate was 96.6%, being 100% in the submerged group and 93.8% in the non-submerged group. This difference was, however, statistically not significant.

The failed implant was successfully replaced 3 months after its removal.

It should be noticed that among the 14 submerged implants placed, three demonstrated a minimal self-exposure of the cover screw. It is important to note that these exposures were limited to the occlusal portion of the mucosa and that the implant necks were never exposed. In the aforementioned three cases, the author’s choice was to change the cover screw with the healing cap, without the elevation of a flap.

BOP

BOP was recorded at the moment of implant loading with the provisional restoration, at the moment of the delivery or the final restoration and at the 1-year follow-up visit.

The non-submerged group showed 19% BOP+ sites at the moment of loading with the provisional restoration, 18% BOP+ sites at the delivery of the final prosthesis and 20% BOP+ sites at the 1-year follow-up visit. The submerged group showed, respectively, 16%, 17% and 21% BOP+ sites at the same intervals. No statistically significant differences in the BOP+ distribution between the study groups at any of the different observations were found (P = 0.38 at provisional loading, P = 0.47 at definitive loading and P = 0.51 at the 1-year follow-up visit).

Variation of the mucosal margin (REC)

Table 2 shows that there were no statistically significant differences between each group’s mean values at baseline and at any further stage of the study (P = 0.47 at baseline, P = 0.4 provisional loading, P = 0.61 at definitive loading and P = 0.33 at the 1-year follow-up visit). The comparisons within each group showed that the recession of the mucosal margin after the surgery was statistically significant for both groups (P = 0.001). This result demonstrated that soft tissue recession occurred after immediate implant placement in this study regardless of submerged or non-submerged implant healing.

Table 3 describes the frequency of midfacial vestibular recessions at the 1-year follow-up visit. The differences in tissue biotypes are also taken into consideration.

Table 2. Recessions (REC) (mm) calculated as the differences between the measurements taken before tooth extraction and at different stages of treatment

<table>
<thead>
<tr>
<th>Group</th>
<th>Provisional loading</th>
<th>Definitive loading</th>
<th>1-year follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>T</td>
<td>Mean</td>
<td>0.93</td>
<td>0.73</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>1.03</td>
<td>0.79</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>95% CI</td>
<td>0.47/1.53</td>
<td>0.79</td>
</tr>
<tr>
<td>S</td>
<td>Mean</td>
<td>0.69</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>95% CI</td>
<td>0.33/1.34</td>
<td>0.67</td>
</tr>
</tbody>
</table>

There were no statistically significant differences in the mean REC values between submerged and non-submerged groups. The comparison within groups demonstrated significant recession occurring at provisional loading, at definitive loading and at 1-year follow-up visits when compared with baseline (P = 0.001).

CI, confidence interval; DP, distal papilla; GM, gingival margin; IM, incisal margin; MP, mesial papilla; SD, standard deviation.
The statistical analysis found no differences between the two groups for the distribution of tissue biotypes \((P = 0.71)\), showing a homogeneous composition of the two samples. No statistically significant differences were also found between the two groups in the distribution of recession types \((P = 0.82)\), indicating that the tissue healing patterns did not seem to influence the extent of recession. When both groups were pooled together in order to determine the influence of tissue biotype on the recession amount, it has been found that, regardless of the tissue healing pattern, implants placed in patients with a thin periodontal biotype showed more recession than implants placed in cases of thick periodontal tissues \((P = 0.03)\).

**Height of KT**

Table 4 shows the results for KT height.

There was no statistically significant difference between each group’s mean values at baseline \((P = 0.47)\). At the time of implant loading with provisional restoration, the difference between the mean KT values in the two groups was statistically significant: the non-submerged group demonstrated minimal change in KT height \((0.27 \text{ mm})\), while the submerged group showed \(1.71 \text{ mm} \) of KT loss \((P = 0.002)\). These changes were almost the same at the time of final restoration \((P = 0.003)\) and were still statistically significant at the 1-year follow-up visit \((P = 0.007)\).

**CBL**

Mean marginal bone resorption at the moment of provisional loading was \(0.26 \pm 0.34 \text{ mm} \) (median \(0.5 \text{ mm} \), 95% CI: \(0.08–0.46 \text{ mm} \)) for the non-submerged group and \(0.46 \pm 0.4 \text{ mm} \) (median \(0.5 \text{ mm} \), 95% CI: \(0.29–0.75 \text{ mm} \)) for the submerged group. At the definitive loading, crestal bone resorption was \(0.54 \pm 0.33 \text{ mm} \) (median \(0.5 \text{ mm} \), 95% CI: \(0.42–0.75 \text{ mm} \)) for T group implants and \(0.58 \pm 0.56 \text{ mm} \) (median \(0.5 \text{ mm} \), 95% CI: \(0.28–0.91 \text{ mm} \)) for S group fixtures. At the 1-year follow-up visit mean bone loss was \(0.54 \pm 0.33 \text{ mm} \) (median \(0.5 \text{ mm} \), 95% CI: \(0.42–0.75 \text{ mm} \)) in the non-submerged group and \(0.63 \pm 0.53 \text{ mm} \) (median \(0.5 \text{ mm} \), 95% CI: \(0.37–0.95 \text{ mm} \)) in the submerged group. No statistically significant differences in the mean CBL values were found between the T and the S groups at any stage of the treatment \((P = 0.28 \text{ at provisional loading}, P = 0.16 \text{ at definitive loading and } P = 0.3 \text{ at the 1-year follow-up visit})\).

**Discussion**

The aim of the present study was to compare the clinical outcome of submerged vs. non-submerged TE implants placed in fresh extraction sockets. Because many variables may affect the clinical results of implants placed in extraction sockets, the authors attempted to limit the influence of other factors.

For this reason, it has been decided to select only sockets with \(<2 \text{ mm} \) of HDD, where there is evidence that augmentation procedures are not necessary \((\text{Paolantonio et al. 2001; Chen et al. 2004})\). Tapered implants were chosen in order to reduce the distance between the implant and the extraction sockets’ walls and to improve attainment of primary stability \((\text{Akkocaglu et al. 2005; Lang et al. 2007})\).

Only one implant was lost during the study, belonging to the non-submerged group. The reason for this failure may be related to a prosthetic overload because the removable prosthesis was not trimmed sufficiently. For this reason, it is the authors’ opinion that this failure was related to a clinical mistake rather to with the healing pattern. This implant has been replaced successfully a few months after its removal.

The composition of the two study groups was homogenous, because no statistically significant differences were found at the
screening visit for any of the parameters studied between the two groups.

Because no differences were found between the study groups in the distribution of the mPI for oral implants at any subsequent stage of the study, it seems that the different treatment modalities do not modify this outcome.

The mean PPD values did not differ significantly between the two groups. The mean PPD values recorded in the present study are consistent with PPD measurement published in previous reports for implants inserted into healed sites [Buser et al. 1990; Apse et al. 1991; Salvi & Lang 2004]. Also, the BOP rate appeared to be consistent with a previously published study [Nishimura et al. 1997].

In terms of the coronal-apical position of the mucosal margin after immediate implants, a previous paper reported 0.75 mm of mean soft tissue recession [Cornelini et al. 2005]. Flapless placement of immediate implants showed 0.55 mm of mean soft tissue recession [Kan et al. 2003]. These differences between the two studies appear to be clinically irrelevant.

A recent study demonstrated soft tissue recession ranging from 1 to 3 mm in one-third of the cases, and <1 mm of recession in the remaining two-thirds of the sample [Chen et al. 2007].

The present study, in accordance with previous reports, demonstrated approximately 1 mm of mean recession, regardless of the type of treatment performed. This outcome suggested that some recession occurs when immediate implants are placed, but this is not related to the submerged or the non-submerged procedure. This study also suggested that, for soft tissue recession, the tissue biotype could be more important than the healing procedure [$P = 0.034$]. It should be noticed that in the present report a similar amount of soft tissue recession was recorded at the interproximal papillae and at the midfacial aspect of the crown.

According to previously published studies on bone healing after extractions, vertical and horizontal bone resorption is expected, regardless of implant insertion immediately after extraction [Covani et al. 2003, 2007; Araujo et al. 2005]. It may be speculated that soft tissue recession may be related to the reduction of hard tissue support found in both study groups. It should be noticed that in the present report no direct measurement of the buccal bone width and height could be performed because an implant exposure procedure was performed only in the submerged group.

The main statistically significant finding in the present study is related to the height of KT. The results of the present study demonstrated a statistically significant loss of KT with the submerged healing. This was probably caused by the coronal repositioning of the flap during the first surgical phase that was necessary to achieve complete wound closure.

Mean interproximal crestal bone resorption did not differ between the two study groups, meaning that the decision regarding a submerged or a non-submerged procedure does not influence this parameter. It should be noticed that no definitive conclusions might be drawn for this parameter, because the radiographs taken in the present study were not standardized. However, great care was recommended to the clinicians to ensure a parallel position of the film and the implant axis using the paralleling technique [Bragger 1994]. The mean CBL values found in our material at the 1-year follow-up visit [0.54 mm in the T group and 0.63 mm in the S group] are similar to the results of previous studies, ranging from 0.26 to 0.5 mm of bone resorption [Kan et al. 2003; Cornelini et al. 2005].

Conclusions

With the limitations of the present study, it might be concluded that immediate implants placed with a submerged or a non-submerged technique show similar success and survival rates with similar behavior of peri-implant hard and soft tissues, including a mean of ~1 mm of vertical recession of the papillae and the midfacial gingival margin when compared with the soft tissue levels before tooth extraction. Significant reduction of the width of KT was observed when using the submerged approach.

The data obtained demonstrate that, with a horizontal peri-implant defect ≤2 mm, there is no need to advance the flap and choose a submerged approach.

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